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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,174	07/22/2005	Gerard Remkes	2565/132	7919
26646	7590	02/23/2010	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004				BASS, DIRK R
ART UNIT		PAPER NUMBER		
1797				
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02/23/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/543,174	REMKES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DIRK BASS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 October 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 16-40 is/are pending in the application.  
 4a) Of the above claim(s) 16-22,31-34,37 and 38 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 23-30, 35, 39-40 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Applicant's request for continued examination filed November 10, 2009 is acknowledged. Claims 16, 19, 23, and 26 are amended. Claims 16-40 are pending and further considered on the merits.

### ***Response to Amendment***

In response to applicant's amendment, the examiner modifies the grounds of rejection set forth in the office action dated August 31, 2009.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 16-22, 31-34, 37-38, drawn to a method for supplying a dialyser with dialysing fluid, classified in class 604, subclass 4.
  - II. Claims 23-30, 35, 39-40, drawn to an apparatus for supplying a dialyser with dialysing fluid, classified in class 210, subclass 96.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a materially different process such as one where concentrated dialysis fluid is pre-diluted by hand and incorporated into a receiving unit, thereby forgoing the dilution step.
3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Jocelyn Ram on February 19, 2010 a provisional election was made with traverse to prosecute the invention of group II, claims 23-30, 35, 39-40. Affirmation of this election must be made by applicant in

replying to this Office action. Claims 16-22, 31-34, 37-38 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 23-30, 35, 39-40** are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Connell et al., US 5744027 (Connell).

9. Regarding claims 23 and 26, Connell discloses an apparatus for supplying a dialyser of a dialysis unit with a dialysing fluid (abstract, fig. 1A-B) comprising:

- a. At least one receiving unit for dialysing fluid concentrate (REF 116, fig. 1B);
- b. Means for providing water for diluting the dialysing fluid concentrate (REF 82, fig. 1A);
- c. Means for mixing the dialysing fluid concentrate and the water (REF 120, fig. 1B); and
- d. A control and calculating unit (col. 15, l. 65-col. 16, l. 15 and REF 516, fig. 7).

10. Regarding the limitations reciting *configured to* language, the examiner considers these to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02). The examiner reminds applicant that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

11. Furthermore, Connell discloses that the control and calculating unit is *capable of* setting a dialysing fluid flow rate as recited in claim 23 (col. 15, l. 65 - col. 16, l. 15 and col. 17, l. 33-44).

12. Regarding claim 24, the limitation "configured to..." is deemed to be a statement with regard to the intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02. The examiner reminds applicant that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

13. Furthermore, Connell discloses that the control and calculating unit is *capable of* setting a dialysing fluid flow rate as recited in claim 24 (col. 15, l. 65 - col. 16, l. 15 and col. 17, l. 33-44).

14. Regarding claim 25, the limitation "configured to..." is deemed to be a statement with regard to the intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02. The examiner reminds applicant that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

15. Furthermore, Connell discloses that the control and calculating unit is *capable of* performing a test to determine the volume of dialysing fluid concentrate in the receiving unit (col. 17, l. 22-47).

16. Regarding claim 27, Connell discloses means for discharging the pre-set residual volume of the dialysing fluid concentrate to waste via a waste discharge outlet (REF 66, 166, and 198, fig. 1A-B). The "wherein..." limitations are considered to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a

***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02).

17. Regarding claim 28, Connell discloses means for mixing the pre-set residual volume of the dialysing fluid concentrate with water (REF 120, fig. 1B). The “wherein...” limitation is considered to be a statement with regard to the intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02).

18. Claim 29 is considered to be a statement with regard to the intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02).

19. Regarding claim 30, Connell discloses means for inputting data (fig. 7-11).

20. Regarding claim 35, Connell discloses an apparatus comprising two receiving units (REF 116, 112, fig. 1B).

21. Regarding claim 39, Connell discloses means for discharging the pre-set residual volume of the dialysing fluid concentrate to waste via a waste discharge outlet (REF 66, 166, and 198, fig. 1A-B). The “wherein...” limitations are considered to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02).

22. Claim 40 is considered to be a statement with regard to the intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02).

### ***Response to Arguments***

23. Applicant's arguments with respect to claims 23 and 26 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

/DRB/  
Dirk R. Bass